

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1-18, 20, 21 and 23 are pending, and claims 6, 18, 20, 21 and 23 are under consideration. By the present amendment, claims 1-5 and 7-18 are canceled. Claim 6 is amended to more specifically recite certain aspects of the invention. Support for these amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. Specific support for lung tumor polypeptides being expressed at levels at least two-fold greater in tumor tissue as compared to normal tissue is provided, *e.g.*, on page 65, lines 1-4. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Information Disclosure Statement

Applicants thank the Examiner for supplying an initialed copy of Form PTO-1449 corresponding to the Fourth Supplemental Information Disclosure Statement. However, Applicants note that the first cited reference, AA, Milne Edwards *et al.* was not initialed. Applicants respectfully request that the Examiner provide Applicants with an additional copy of this Form PTO-1449, wherein this reference has been initialed. For the Examiner's convenience, a copy of the unsigned Form PTO-1449 is provided herewith along with a copy of Milne Edwards.

Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 6, 18, 20, 21 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being supported by a specification enabling for methods using a binding agent that binds to a polypeptide having at least 90% identity with a polypeptide encoded by SEQ ID NO:808 or any protein containing a fragment of the polypeptide encoded by SEQ ID NO:808. In addition, the Action alleges that the specification does not adequately define a predetermined

cut-of value. Applicants note that the Action indicates that the instant specification is enabling for methods for detecting the presence of lung adenocarcinoma in a human patient by detecting the presence of a polypeptide encoded by SEQ ID NO:808 or by detecting an increase in the level of said polypeptide relative to the level in a normal cell.

Applicants respectfully traverse this basis of rejection and submit that the skilled artisan would be able to practice the claimed invention based upon the teachings of the specification. However, without acquiescence to this basis of rejection, claim 18 has been canceled and claim 6 has been amended to recite “a binding agent that binds to the polypeptide encoded by the entirety of the polynucleotide sequence of SEQ ID NO:808,” thus clarifying that the polypeptide to which the binding agent is capable of binding is the full length polypeptide encoded by SEQ ID NO:808.

In addition, claim 6 has been amended to remove reference to a predetermined cut-off value and to indicate that the presence of a lung cancer is determined by comparing the amount of polypeptide encoded by SEQ ID NO:808 in a biological sample from a patient to the amount present in a sample of normal lung tissue, wherein an at least two-fold greater amount in the biological sample as compared to the normal lung tissue sample is indicative of the presence of a lung cancer in the patient. Support for this amendment is provided in the instant specification, including, *e.g.*, on page 65, lines 1-4.

In light of these amendments and remarks, Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 6, 18, 20, 22 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter not adequately described in the specification. More specifically, the Action alleges that the specification does not adequately describe the genus of polypeptides having at least 90% identity with a polypeptide encoded by SEQ ID NO:808 and polypeptides comprising fragments of a polypeptide encoded by SEQ ID NO:808.

Applicants respectfully traverse this basis of rejection and submit that the instant specification adequately describes the claimed genus of variants and fragments of a polypeptide

encoded by SEQ ID NO:808. Nonetheless, without acquiescence to this basis of rejection, claim 18 has been canceled and claim 6 has been amended to recite “a binding agent that binds to the polypeptide encoded by the entirety of the polynucleotide sequence of SEQ ID NO:808,” thus clarifying that the polypeptide to which the binding agent is capable of binding is the full length polypeptide encoded by SEQ ID NO:808.

Accordingly, Applicants respectfully request that the Examiner withdrawn this basis of rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 6, 18, 20, 21 and 23 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite in the recitation of “predetermined cut-off value.” The Action alleges that the specification fails to provide an adequate definition of the phrase and there is no art recognized definition of the phrase.

Applicants respectfully traverse this basis of rejection and submit that the claims are definite in the recitation of “predetermined cut-off value.” Applicants maintain their position that the skilled artisan would readily understand the meaning of the phrase “predetermined cut-off value,” based upon general knowledge in the field and the description in the instant specification. In addition, Applicants submit that the instant specification explicitly describes exemplary cut-off values and methods of determining the same. However, without acquiescence to this basis of rejection, claim 18 has been canceled and claim 6 has been amended to remove reference to a predetermined cut-off value and to indicate that the presence of a lung cancer is determined by comparing the amount of polypeptide encoded by SEQ ID NO:808 in a biological sample from a patient to the amount present in a sample of normal lung tissue, wherein an at least two-fold greater amount in the biological sample as compared to the normal lung tissue sample is indicative of the presence of a lung cancer in the patient, thereby obviating this basis of rejection.

Applicants respectfully request that this basis of rejection be withdrawn in light of these amendments.

Application No. 09/658,824
Reply to Office Action dated September 8, 2003

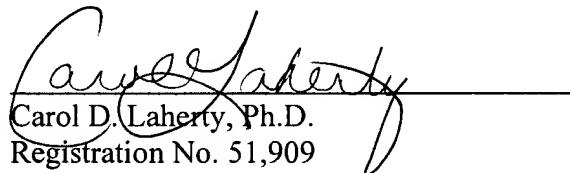
The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully request allowance of claims 6, 20, 21 and 23. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention, the Examiner is requested to contact the undersigned at (206) 622-4900.

Respectfully submitted,

Tongtong Wang et al.

SEED Intellectual Property Law Group PLLC


Carol D. Laherty, Ph.D.
Registration No. 51,909

CDL:jto

Enclosure:

Postcard

Copy of Sheet 1 of previously submitted Form PTO-1449

Copy of Milne Edwards et al.

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092

Phone: (206) 622-4900

Fax: (206) 682-6031

\424172_1.DOC